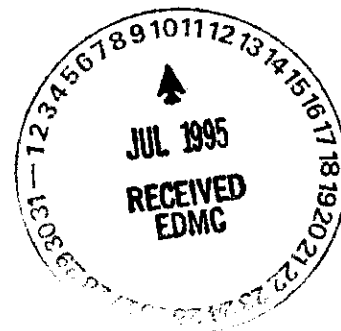PNL Administrative/Technical Procedures

Quality Assurance Manual

May 1995

Prepared for the U.S. Department of Energy
under Contract DE-AC06-76RLO 1830

Pacific Northwest Laboratory
Operated for the U.S. Department of Energy
by Battelle Memorial Institute

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PNL Administrative/Technical Procedures

Quality Assurance Manual

J. E. McGarrah

May 1995

Pacific Northwest Laboratory
Richland, Washington 99352

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BATTELLE MEMORIAL INSTITUTE
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QUALITY ASSURANCE MANUAL

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Approved By: _____   6/30/94

    JW Smith, Director, Quality Programs   Date

Introduction

Quality Assurance Program

To provide clients with quality products and services, Pacific Northwest Laboratory (PNL) has established and implemented a formal Quality Assurance (QA) Program. These management controls are documented in this manual (PNL-MA-70) and its accompanying standards and procedures. The QA Program meets the basic requirements and supplements of ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*, as interpreted for PNL activities. Additionally, the quality requirements are augmented to include the Total Quality approach defined in the Department of Energy Order 5700.6C, *Quality Assurance*.

This manual provides requirements and an overview of the administrative procedures that apply to projects and activities.

Use of Manual

To better understand and use the manual, please note:

- significant changes made by the latest revision are indicated by background shading

- Section 1.1, "Organization", of the manual includes broad QA Program responsibilities; the remaining sections delineate the specific purpose and requirements for elements of the QA Program

- Section 2.1, "QA Program", describes the graded approach to quality application used at PNL (based on potential consequences of an error or failure) and the preparation of QA plans

- Section 2.1, "QA Program", identifies when the Good Practices Standard, Part 2 of the manual is used

- approval of the Documentation Systems Department Manager is required to send copies of this manual outside of PNL

- revisions to this manual will be approved by the Quality Programs Director for the Director of PNL. Any waiver of requirements is approved in writing by the Quality Programs Director

- suggestions for changes to this manual should be forwarded to the Documentation Systems Department Manager.

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1.1 Organization

Purpose

To define and document the organizational structure, functional responsibilities, levels of authority, lines of communication, and organizational interfaces (internal and external) of the Quality Assurance Program and to ensure that quality-related activities are performed by the responsible organization.

Requirements

When fully applied, the requirements as described in the PNL-MA-70 administrative procedures and referenced documents in the Policy and Procedures System meet the requirements of Basic Requirement 1 and Supplement 1S-1 of ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*. Additionally, the quality requirements are augmented to include the Total Quality approach defined in the Department of Energy Order, 5700.6C, *Quality Assurance*. Requirements are summarized below:

Organizations responsible for ensuring that an appropriate Quality Assurance (QA) Program has been established, and for verifying that activities affecting quality have been correctly performed shall have sufficient authority, access to work areas, and organizational freedom to:

- identify quality-related problems

- initiate, recommend, or provide solutions to quality-related problems through designated channels

- verify implementation of solutions

- ensure that further processing, delivery, installation, or use is controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.

A stop work request shall be issued for activities not in substantial compliance to QA Program requirements or for activities for which corrective action is not implemented in a timely manner. Completion of appropriate corrective action shall be verified before a stop work request is lifted.

The Quality Programs Director shall have direct access to the Director, PNL and shall report at a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations, to achieve PNL quality performance objectives.

PNL's organizational structure and responsibility assignments shall be such that:

- quality is achieved and maintained by those who have been assigned responsibility for performing work

- quality achievement is verified by those not directly responsible for performing the work.

Organization

The Pacific Northwest Laboratory is managed by the Director, PNL. Laboratory technical center managers and directors, including the Quality Programs Director, report directly to the Director, PNL.

The Quality Programs Directorate is comprised of the:

- Documentation Systems Department

- Process Quality Department

- Quality Planning and Assessment Department

- support staff for continuous improvement.

Responsibilities

Responsibilities related to the QA Program are defined in the various sections of this manual and the administrative procedures. The individuals responsible for establishing and executing the PNL QA Program may delegate any or all of the work to others but shall retain responsibility thereof. The significant management level responsibilities are summarized below:

Director, PNL

Ultimate management responsibility for the establishment and enforcement of PNL's continuous improvement (including QA) policy and program.

Issue management guides covering responsibility and authority.

Ensure effective implementation of the QA Program.

Delegate the authority for establishing and maintaining the QA policy and program and for facilitating QA Program implementation to the Quality Programs Director.

Center Managers and Directors

Report directly to the Director, PNL.

Ensure appropriate quality in research, construction, and operations under their direction.

Ensure their staff comply with applicable QA requirements as specified by the Policy and Procedure System and PNL-MA-70, QA Plans, and referenced procedures.

Ensure that commitments to the client are correct and are met.

Recruit, train, assign, and manage technical and technical support staff, including qualifying and certifying them when required.

Arrange for adequate facilities and equipment needed for assigned staff to achieve quality objectives.

Ensure that appropriate administrative procedures, technical procedures, and instructions are developed, approved, and available for staff use, as appropriate.

Ensure that work performed is consistent with work requirements and commitments to the client.

Initiate timely corrective action within their areas of responsibility when deficiencies are noted.

Contracts Department Manager   Monitor the client contractual interface and ensure that quality-related problems with contract activities are resolved.

Quality Programs Director   Reports directly to the Director, PNL, and has been delegated the responsibility to establish and maintain PNL's QA policy and program, and to facilitate QA Program implementation.

Approve the initial issue and revisions to the PNL QA manual and approve quality-related administrative procedures.

Issue stop work requests on activities not in substantial compliance with QA Program requirements and activities for which corrective action is not implemented in a timely manner.

Conduct independent assessments, and assessments upon request, of activities to determine implementation effectiveness of the QA Program.

Delegate to the Quality Programs Department Managers the authority for administration and coordination of the QA Program.

Quality Programs Directorate Responsibilities

Represent PNL on QA matters with clients as delegated by the Quality Programs Director.

Assist in the development of QA/Management Plans when requested.

Assist staff members with the application of QA requirements to their activities.

Provide technical support to programs/projects to facilitate implementation of QA requirements.

Provide independent quality assurance inspection as necessary to ensure adequate verification coverage of product quality.

Provide guidance and assistance in the implementation of the quality assurance program for measuring and test equipment.

Request, track, and obtain timely corrective action for activities not in compliance with QA Program requirements.

Inform the Quality Programs Director and the Director, PNL, of quality-related problems and obtain resolution when required.

Interpret QA Program requirements and determine appropriate application.

Maintain a QA requirements baseline to assure adequate implementation and change control.

Develop and maintain the QA Program for PNL as documented in PNL-MA-70, *Quality Assurance Manual,* and PNL-MA-531, *Quality Programs Instructions,* including concurrence with the administrative procedures for compliance with QA

Program requirements, and review and approval of the instructions for the Quality Programs staff.

Develop, implement, and deploy an independent internal QA assessment program to ensure adequate oversight of project, program, and functional activities at PNL.

Provide quality-related training support to management, as needed, to meet performance, qualification, and compliance objectives.

2.1 QA Program

Purpose

Planning assists in the proper application of requirements to research and development projects, construction projects, support services, and facility operations. Using a graded approach, the PNL Quality Assurance (QA) Program provides for planning and accomplishing activities affecting quality under suitably controlled conditions. The PNL QA Program as described in this manual and documented references, applies to all organizational elements of PNL.

Requirements

The PNL QA Program has been designed to ensure that an appropriate QA Plan is established and implemented commensurate with PNL's responsibility for:

- health and safety

- environmental protection

- reliability and continuity of operation

- acquisition of valid research and development data.

The PNL QA Program has also been designed to comply with the basic requirements and supplements of ASME NQA-1, *Quality Assurance Requirements for Nuclear Facilities*, as interpreted for the activities and services performed by PNL. When fully applied, the methods in the administrative procedures and referenced documents in the Policy and Procedure System, and the requirements in this section meet the applicable requirements of DOE Order 5700.6C, *Quality Assurance*, and NQA-1 Basic Requirement 2 except the third paragraph which is addressed in Manual Section 2.2, "Training".

The impact level and/or safety class shall be determined using established criteria. Management Plans/Quality Assurance (MP/QA) Plans shall be prepared, reviewed, approved, issued, implemented, and revised for all Impact Level I and II research projects, support services, Work Orders from Hanford Contractors, and construction projects. Quality program requirements for Safety Class systems, structures, and components (SSCs) for facilities and their operation shall be documented in a MP/QA Plan (for the remainder of this manual section, the generic term "work" will be used to represent all of these activities performed by PNL for both internal and external clients). The MP/QA Plans shall identify the requirements of the PNL QA Program and any additional QA requirements from the client that apply to the work covered by the plan. Before a MP/QA plan is closed-out, outstanding QA related action items shall be resolved, records shall be completed and transmitted as required, and leftover or archival test material shall be shipped or disposed in accordance with applicable regulations and agreements between PNL and the client.

Appendix 1 provides a listing of the Administrative Procedures applicable to Impact Level I and II work, and Safety Class SSCs. Impact Level III and Non-Safety Class SSCs work is covered by the Good Practices Standard, PNL-MA-70, Part 2. PNL-MA-531, *Quality Programs Instructions*, includes instructions for the Quality Programs staff for activities such as audits and surveillances that are performed by Quality Programs.

Appendix II provides a flow diagram describing the Project QA Planning process. Appendix III provides a listing of the parts of PNL-MA-70.

Responsibilities

Significant responsibilities include:

Director, PNL

Ensuring effective implementation of the QA Program.

Delegating the authority for establishing, implementing, and maintaining the QA Program to the Quality Programs Director.

Quality Programs Director

Approving and issuing quality assurance manuals and related instructions necessary to administer the QA Program.

Reviewing and approving quality-related documentation as required by the QA Manual implementing procedures and MP/QA Plans.

Line Managers

Monitoring the implementation of the QA Program within their organizations.

Approving MP/QA Plans, including the impact levels, for cognizant managers that report to them.

Approving impact level determinations for PNL work.

Cognizant Manager (e.g., Project Manager or equivalent)

Determining impact levels for PNL work or Safety Class SSCs.

Providing MP/QA Plans for Impact Level I or II work.

Obtaining the concurrence of Process Quality and the approval of his/her Line Manager on MP/QA Plans.

Implementing, reviewing, revising, and closing out MP/QA Plans.

QA Plans

Research and Development Projects and Work Orders

The Cognizant Manager shall determine the impact level for all R&D projects and for activities covered by work orders from Hanford contractors.

The Cognizant Manager shall document the impact level and reasons for the level selected, obtain the required approvals, and send information copies to Quality Programs.

For Impact Level I or II projects and work orders from Hanford contractors, a Project MP/QA Plan shall be implemented before work progresses beyond the planning stage.

Project MP/QA Plans shall be prepared and approved, unless the client requests a different QA Program or a different QA Plan format (e.g., Good Laboratory Practices regulations found in 21CFR58 and 40CFR792). Prior approval of the Quality Programs Director is required to use a different QA Program. Prior

approval of a Lead Quality Engineer is required to use a different QA Plan format.

Support Service Activities

Support services include but are not limited to:

- craft services

- routine analytical chemistry laboratories

- laboratory safety

- records management and document control

- procurement and subcontracts.

Support service Line Managers, with the assistance of a Quality Programs representative, shall at least annually review the support services they provide and determine which services should have an Activity MP/QA Plan. Work that is adequately covered by a Project MP/QA Plan does not require an Activity MP/QA Plan. However, an Activity MP/QA Plan should normally be prepared for support services that involve routine and repetitive tasks that can impact the quality of Impact Level I or II projects or Safety Class SSCs for which they provide support services. The review shall be documented in a letter from the Support Services Line Manager to his/her Manager with a copy to the Process Quality (PQ) Department. The letter shall include the planned issue date for any needed MP/QA Plans.

Service Activity MP/QA Plans shall be prepared and approved in a manner similar to that described in the Administrative Procedure for project QA Plans. Prior approval of the Quality Programs Director is required to use a different QA Program. Prior approval of a Lead Quality Engineer is required to use a different QA Plan format.

Construction Projects

Construction project impact levels shall be determined by the Manager of the using PNL organization. The Project Manager shall ensure that systems, structures, and components are assigned a safety class. Project MP/QA Plans for Impact Level I & II and Safety Class projects shall be prepared and approved as described in the administrative procedure for QA Plans. Information copies shall be sent to the PQ Department. The project MP/QA Plan shall be prepared and approved early enough in the project so that appropriate requirements can be incorporated into the definitive design.

To ensure the following documents include appropriate QA Program requirements, review and approval of the PQ Department Manager before transmittal is required.

- Draft statements of work and draft advertisements for the "Commerce Business Daily" for use by DOE to obtain the services of offsite A/Es for DOE projects.

- For DOE funded projects, the functional design criteria, conceptual design reports, statements of work, or letters of instruction for the onsite A/E and project management plans.

- For Battelle funded projects, the functional design criteria and conceptual design packages.

The impact level and safety class and the rationale for their selection are required in the functional design criteria and conceptual design documents.

Facility Operation and Modification

For all modifications to a facility, the Cognizant Building Manager shall determine the safety class for the modification and include the safety class on the Engineering Request before forwarding the request to Facilities Engineering. Facilities Engineering shall review the assigned safety class and resolve any differences with the Building Manager. The safety class shall also be noted on the Facility Modification Permit. For Safety Class SSC modifications, a Modification MP/QA Plan shall be prepared by Facilities Engineering, with the assistance of a PQ Representative, before the design of the modification is started.

The Facilities Operations Section Manager and the individual Building Managers shall review significant changes in the use of the buildings to determine if changes, additions, or deletions of Facility MP/QA Plans are required. This review shall be documented and include a schedule for any revisions required to the Facility MP/QA Plans.

Appendix I - PNL-MA-70 Procedures

Number	Title
PAP-70-101	Communication and Commitment (Interface) Control
PAP-70-201	Indoctrination and Training
PAP-70-203	Qualification and Certification of Inspection and Test Personnel
PAP-70-205	Quality Assurance Plans
PAP-70-206	Controlling Work Received from Hanford Contractors
PAP-70-207	Quality Control Requirements for Safety Class Systems, Structures, and Components
PAP-70-208	Impact Levels
PAP-70-301	Hand Calculations, General
PAP-70-302	Assurance and Control of Engineering Design
SCP-70-312	Determination of Software Requirements
SCP-70-313	Final Internal Development Review of Software and Documentation
SCP-70-314	Software Configuration Management
SCP-70-315	Conversion Testing Verification, and/or Validation of Software
SCP-70-316	Software Application Control
SCP-70-317	Transfer of Software, Data, and/or Documentation
SCP-70-318	Control of Databases
CAP-70-401	Preparation of Requests for Proposals and Award of Contracts/Agreements
PAP-70-401	Purchase Requisitions
PAP-70-402	Control of Suspect/Counterfeit Items
PAP-70-404	Obtaining Services
PAP-70-501	Preparation and Approval of Administrative Procedures
PAP-70-601	Document Control
PAP-70-602	Procedure and Instruction Change Control and Change Request
PAP-70-604	Independent Technical Review
PAP-70-605	Document Control - Furnished Documents
PAP-70-606	Peer Review
CAP-70-701	Proposal Evaluation Supplier/Subcontractor Selection, and Contracts/Agreements Administration (Post Award)
PAP-70-702	Preparation and Use of Inspection/Test Instructions (ITIs)
PAP-70-704	Source Inspections, Tests, and Surveillances
PAP-70-706	Receiving Inspection
PAP-70-801	Identification and Control of Test Materials (Testing and Analysis)
PAP-70-803	Item Identification and Control
PAP-70-901	Control of Processes
PAP-70-902	Control of Special Processes
PAP-70-1001	Independent Inspection
PAP-70-1101	Test Planning, Performance, and Evaluation

Appendix I - PNL-MA-70 Procedures

Number	Title
PAP-70-1201	Calibration Control System
PAP-70-1202	Calibration Control System for Radiation Detection Equipment
PAP-70-1301	Handling, Storage, and Shipping
PAP-70-1401	Inspection and Testing Status and Tagging
PAP-70-1501	Nonconformance Reports
PAP-70-1502	Deficiency Reports
PAP-70-1602	Corrective Action
PAP-70-1701	Records System

This Appendix or the procedures represented by this Appendix
may be revised or changed without requiring
a corresponding revision of this manual section.

PROJECT QA PLANNING FLOW

CONCURRENCE

APPROVAL

IMPLEMENT QA MANAGEMENT PLAN

PREPARE QA MANAGEMENT PLAN

IMPLEMENT SOP

REQUIREMENTS CURRENT?

IMPACT LEVEL 1?

REQUIREMENTS CURRENT?

SPECIAL QA PROGRAM CURRENT?

DETERMINE IMPACT LEVEL

CONCURRENCE

APPROVAL

NEW WORK OR MAJOR SCOPE CHANGE

YES NO

QA DIRECTOR

LEAD QUALITY ENGINEER

LINE MANAGER

ES&H SAFETY REVIEW

PROJECT MANAGER
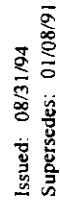
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Appendix III - Quality Assurance Documents

PNL-MA-70 PART 1

Quality Assurance Program Description

PNL-MA-70 PART 2

Good Practices Standard

PNL-MA-70 PART 3

Procedures for Quality Assurance Program

•Contracts Administrative Procedures

•PNL Administrative Procedures

•Software Control Procedures

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2.2 Training

Purpose

To support the achievement of acceptable work performed at PNL, personnel performing the work must have achieved and maintained proficiency in both the technical and quality assurance aspects of their job functions. Essential parts of the orientation and training program for ensuring personnel qualifications necessary for proficiency include:

- QA Program orientation

- assignment of work based on qualifications (education and experience)

- training to specific QA and technical aspects of the assigned job function prior to allowing personnel to perform activities which affect quality

- certification to applicable codes and standards

- reassessment of qualifications, certifications, and training, on a regularly scheduled basis and whenever significant changes are made to the job function (e.g., when applicable procedures are revised, when the scope of work changes, etc.)

- maintenance of records of personnel selection, qualification, certification, and training.

Requirements

Detailed instruction for the implementation of the training program for personnel performing activities at PNL is provided in the administrative procedures and in referenced documents in the Policy and Procedures System. The significant requirements of the program are summarized below.

- All new staff members will receive an initial orientation into the PNL-MA-70 QA program.

- Personnel performing independent inspections are to be certified in accordance with NQA-1, Supplement 2S-1 and DOE Order 5700.6C.

- Personnel performing nondestructive examination (NDE) for acceptance purposes are to be certified in accordance with SNT-TC-IA.

- Lead Auditors are to be certified in accordance with the requirements of NQA-1, Supplement 2S-3, and DOE Order 5700.6C.

- Specific qualification, training, and certification requirements, for activities other than those mentioned above, will be determined on a case-by-case basis by Line, Project, or Activity Managers. This determination is based on: the type (scope, complexity, and nature) of work to be performed, the potential effect on quality, and the applicability of other codes or standards.

- Line, Project, and Activity Managers will maintain appropriate records of staff selection, qualification, certification, and training; provide (or arrange for) the required training prior to assigning the staff member to perform work affecting quality; and assess staff qualifications, certifications, and training needs on a regularly scheduled basis, e.g., during staff development reviews.

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3.1 Design Control

Purpose

Proper selection and definition of functional criteria and other design inputs are necessary to ensure that correct bases are established for engineering design. Controls are established for engineering design activities to ensure that outputs in the form of engineering designs and design data comply with functional design criteria and other specified requirements.

Documented planning is necessary to provide early and adequate assurance that the specified requirements can and will be met. Procedures are used to ensure that design activities including analyses, calculations, and the preparation and control of drawings and documents are performed properly and in a consistent and uniform manner. Controlled methods are prescribed to verify that the outputs of engineering design activities comply with functional design criteria and meet specified requirements.

Requirements

When fully applied, the methods included in the administrative procedures for the control of engineering design activities, and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and are based on Basic Requirement 3 and Supplement 3S-1 of NQA-1. These methods do not apply to software controls covered by Section 3.2, "Computer Software", of this manual. The significant requirements from PNL-MA-90, *Design Preparation, Control and Implementation*, and the administrative procedures for control of engineering design activities are summarized in the following paragraph.

When specified by an applicable QA Plan or other governing documents, an Engineering Design Plan (EDP) shall be prepared and implemented. An EDP will be required for Impact Level I and II and Safety Class projects. The scope and specific requirements of the EDP shall be commensurate with the impact level/ safety class and the complexity of the engineering design effort. The EDP shall identify the impact level(s)/ safety class to be applied to the design and the specific actions required. The EDP shall identify client and QA Plan requirements applicable to the engineering design activities to be performed and shall further develop and define specific requirements and responsibilities including the selection and application of procedures for performance of analyses and calculations; performance of design, including preparation of drawings and documents; verification of design; control of drawings and documents; and control of field engineering and changes. The EDP shall cover engineering design activities from the determination of design inputs through the preparation of as-built drawings and documents.

Responsibilities

Significant Responsibilities include:

Lead Organization

Ensuring that client input data to PNL are reviewed and client requirements are identified.

Ensuring that requirements are defined and documented in an Engineering Design Plan (EDP), including QA Plan requirements.

Ensuring the EDP requirements are implemented for performance of analyses, calculations and design; for control of design drawings and documents; for design verification; and for control of field engineering and changes.

Organization Performing Design   Implementing requirements of EDP and applicable procedures, including required reviews or other verification actions and submittal of documentation.

Preparing required analyses, calculations, drawings, and documents.

Quality Programs Staff   Assisting in the preparation of EDPs.

Reviewing and concurring with quality assurance requirements of EDPs.

Reviewing engineering design drawings and documents when required by an EDP.

Participating in formal design reviews when required by an EDP.

3.2 Computer Software

Purpose

Controls are established for the development, modification, acquisition, and use of software to ensure that data produced by the software are valid representations of the natural or other phenomena being modeled. Software design inputs are developed and reviewed to provide a sound basis for the design process. Newly developed or modified software is reviewed to eliminate as many deficiencies as possible before testing and initiating configuration management. Software that has been developed, modified, or acquired is tested to verify and validate its outputs. Configuration management, access control and physical protection are applied to protect the software against unauthorized changes, loss, or deterioration. The application of software is approved, documented, and reviewed to ensure that the application is correct and that problems encountered are properly documented and resolved.

Databases are controlled to ensure that inputs are correct, modifications are made properly, data are protected, and deficiencies are documented, reported, and resolved.

Software controls depend on the classification assigned to the software at the beginning of its development, or upon its acquisition. These controls have no direct relationship to the impact level of the software application.

Requirements

When fully applied, the methods included in the administrative procedures for computer software control, and referenced documents in the Policy and Procedure System meet the requirements in DOE Order 5700.6C and Basic Requirement 3 and Supplement 3S-1 of NQA-1, as interpreted for software. The significant requirements from the administrative procedures are summarized in the following paragraphs. These requirements do not apply to software that is part of a purchased measuring and test equipment system, unless PNL changes the software. The software requirements found in NQA-1, Supplement 11S-2 will be fully addressed with the next revision of the administrative procedures.

Software shall be classified, and requirements for the software shall be determined based on its classification. Newly developed or modified software shall receive an independent technical review. Software shall be verified, and validated when required, through testing. Records of software configuration shall be maintained. Software shall be protected against uncontrolled changes and against loss or damage. Software applications shall be documented. Application problems shall be documented and resolved. Transfers of software to or from PNL shall be approved and documented.

Inputs to data bases shall be verified. Databases and modifications to databases shall be approved. Access to data bases shall be limited. Databases shall be backed up. Deficiencies in databases shall be documented and resolved.

Responsibilities

Significant responsibilities include:

Using Organization

Classifying software and determining the requirements for its control.

Obtaining and resolving independent technical review of newly developed software.

Testing software to verify and validate it.

Controlling software configuration.

Protecting software and databases.

Approving and documenting software applications.

Approving and documenting software transfers.

Controlling inputs, modifications, and access to databases.

4.1 Procurement Document Control

Purpose

Controls are exercised over procurement documents to ensure that the documents adequately specify the requirements needed to obtain an item or service that is satisfactory for its intended use. The correct specification of requirements will also help prevent schedule delays and cost increases resulting from receiving an incorrect item or service. The controls, which are a function of the item's or service's impact level and complexity, are intended to ensure that the item or service is clearly and correctly specified, that the supplier will be capable of providing a quality product, that exceptions or changes are satisfactory to PNL, and that adequate evidence of item or service quality will be provided.

The requirements of this section are closely related to those of Section 7.1, "Control of Purchased Items and Services", which describes how PNL evaluates and selects capable suppliers and verifies the quality of the items purchased. The planning for these activities is done during the preparation of purchase requisitions (PRs). The implementation of Section 4.1 should not be attempted without a review of Section 7.1, "Control of Purchased Items and Services".

Requirements

When fully applied, the methods included in the administrative procedures and procurement instructions for the preparation and review of procurement documents and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 4 and Supplement 4S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

PRs and attachments shall be prepared by PNL personnel who have the appropriate background and information related to the items or services to be procured. The PR and attachments shall contain all technical and quality information necessary to specify clearly the required items or services. Required reviews of the PR shall be obtained and shall include a technical representative, a level 4 manager, and a Quality Programs representative and may include Laboratory Safety, the Pressure Systems Engineer, and others. As appropriate to the procurement, QA clauses shall be invoked to require such actions as preaward evaluation of the supplier, independent receiving inspection, source inspection or source surveillance, and post installation testing.

Responsibilities

Significant responsibilities include:

Requesting Organization

Ensuring that purchase requisitions and attachments contain required technical specification and quality assurance provisions appropriate to the impact level, nature, and complexity of the item or service.

Obtaining review and approval of purchase requisitions, including any changes thereto, by appropriate personnel.

Contracts

Ensuring that the contents of purchase requisitions and attachments are transferred to the appropriate procurement documents before transmittal to prospective suppliers.

Ensuring that changes to procurement documents are processed and fully approved by the affected organizations.

Quality Programs Staff

Reviewing and concurring in requirements for each item or service on each PR presented for review.

Reviewing and concurring in quality-related changes to the subject procurement documents.

4.2 Work Package Control

Purpose

Work Packages (including Work Orders) and their associated documents are prepared, reviewed, and approved in accordance with this section to ensure that the technical and quality assurance requirements transmitted to the performing organization are complete and correct.

Section 7.2, "Control of Work Package Items and Services", and the documents in the Policy and Procedure System, describe the controls that are used after the Work Package has been issued to ensure that the work performed meets the requirements of the Work Package documents.

Requirements

When fully applied, the methods included in the administrative procedures and referenced documents in the Policy and Procedure System meet the applicable requirements in DOE Order 5700.6C and Basic Requirement 4 and Supplement 4S-1 of NQA-1. Since Work Package items and services are obtained from other PNL organizations or from Hanford Contractors, some of the Criterion 4 requirements are not strictly applicable. These include:

- making provisions in the Work Order for right of access -- This right is automatic.

- providing for the reporting of nonconformances experienced by the performing organization -- Nonconformances are required to be reported under the quality assurance programs of PNL and the Hanford Contractors.

- controlling changes resulting from bid evaluations, since there are no bids

- requiring the performing organization to identify spare parts, since very few of the items fabricated would have spare parts

- requiring the performing organization to have a quality assurance program meeting NQA-1, since such programs are already in place.

The significant requirements from the administrative procedures are summarized in the following paragraphs.

Work Packages shall reference or contain statements of work that clearly specify all necessary technical requirements, and all appropriate quality assurance requirements such as the procedures to be used, reviews and approvals of documents furnished by the performing organization, controls over samples and measuring and test equipment, provision for an evaluation of the performing organization by Quality Programs before beginning work, and provision for hold points. Statements of work shall be reviewed and concurred in by the Quality Programs Representative, accepted by the performing manager, and approved by the issuing manager. Changes to Work Package statements of work shall be documented, reviewed, and approved in the same manner as the originals.

Individual increments of work shall be defined in Requests for Work or Requests for Analytical Services that are consistent with the statement of work.

Responsibilities

Significant responsibilities include:

Requesting Organization

Preparing and approving Work Package statements of work that meet the requirements of this section.

Obtaining acceptance of Work Package statements of work by the performing organization, and resolving any differences.

Preparing and issuing Requests for Analytical Services and Requests for Work.

PNL Performing Organization

Accepting Work Package statements of work based on being able to meet all specified requirements before the start of work.

Quality Programs Staff

Reviewing and concurring in Work Package statements of work to ensure that the quality assurance requirements included are appropriate for the assigned impact level and scope of work.

5.1 Instructions, Procedures, and Drawings

Purpose

Instructions, procedures, and drawings are used to ensure that activities affecting quality will be performed consistently and correctly. Activities of an administrative nature are prescribed in administrative procedures. Technical activities affecting quality make use of test instructions, technical procedures, and/or drawings when, without these documents, there would be a significant likelihood of performing the work incorrectly and obtaining unacceptable or undesirable results. The use of these documents and the level of detail required depend on both the impact level and the complexity of the activity.

This section is closely related to Section 6.1, "Document Control", which describes how these documents are controlled (i.e., reviewed, approved, distributed, and changed) and identifies approval authorities.

Requirements

When fully applied, the methods included in the administrative procedures for the application, preparation, and use of instructions, procedures, and drawings and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 5 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Activities affecting quality shall be prescribed by administrative procedures, technical procedures, test instructions, or drawings except when supplier procedures are available for standard items, or when there is a high level of certainty that the activity will be done correctly without them. These documents shall adhere to prescribed formats and content. They shall include appropriate acceptance criteria for verifying that the activity has been accomplished satisfactorily. Selected technical procedures, including procedures for special processes, shall be qualified to demonstrate the procedure will produce acceptable results. Work shall be performed in accordance with these documents.

Responsibilities

Significant responsibilities include:

Project and Line Organizations

Providing and using instructions, procedures, and drawings for the quality-related activities that they perform.

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6.1 Document Control

Purpose

Documents that prescribe activities affecting quality (e.g., instructions, procedures, and drawings) and changes to these, are controlled in order to ensure that the versions used are complete, correct, current, and available at the location of the work. Controls include review, comment resolution, approval, and distribution control.

Reviews, comment resolutions, and approvals are performed to ensure that the documents (including changes) are complete, correct, and practical, satisfy the applicable requirements, and include the appropriate quality assurance requirements.

Distribution is controlled to ensure that document holders have the latest approved versions. Workplace copies are specially controlled to ensure that they are at the workplace before and during the work, and that they are current.

Impact Level II or Safety Class technical procedures do not require independent technical reviews, formal comment resolutions, or distribution control (except for workplace copies). Impact Level I technical procedures require all of these.

Requirements

When fully applied, the methods included in the administrative procedures for the control of documents that prescribe activities affecting quality and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 6 and Supplement 6S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Documents that prescribe activities affecting quality shall be reviewed by knowledgeable reviewers, including Quality Programs staff. Review comments shall be resolved. The documents shall be approved for issuance by designated approval authorities. Distribution of the documents shall be controlled. Workplace copies shall be at the workplace before and during the performance of work, and shall be replaced or updated with approved changes. Changes, except for editorial changes, shall be controlled in the same way as original documents.

Responsibilities

Significant responsibilities include:

Director, Quality Programs

Approving PNL Administrative Procedures (PAPs) and Software Control Procedures (SCPs) for the Director, PNL.

Quality Programs Staff

Controlling the review, comment resolution, approval, and distribution list for administrative procedures.

Reviewing and concurring in drawings and procedures.

Project and Line Organizations

Approving administrative procedures other than PAPs and SCPs.

Approving drawings.

Controlling test instructions, technical procedures, and drawings.

Ensuring the availability and currentness of workplace copies of instructions, procedures, and drawings.

Document Control
Publishing and distributing administrative procedures, and maintaining their table of contents.

Controlling the distribution of other documents as requested.

All Staff Members
Adhering to approved instructions, procedures, and drawings.

7.1 Control of Purchased Items and Services

Purpose

Controls are exercised over procured items and services to ensure that these conform with specified requirements.

Preaward surveys are used to provide assurance of a prospective contractor's current technical/quality assurance capabilities where failure of a deliverable is likely to jeopardize data validity or safety conditions, or cause significant cost impact. Source verification activities are used primarily to help preclude delivery of items or services that have hidden defects or other characteristics difficult to verify after delivery, or which could cause programmatic delays/costs or failure to meet the client's requirements.

Receiving inspection activities are performed to verify conformance of the item and documentation to requirements where failure to do so would cause schedule, cost, safety, or data impact.

The extent to which these controls are applied is dependent on the impact level of the item or service and the need to control an activity to ensure the quality of the item or service.

Requirements

When fully applied, the methods included in the administrative procedures and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 7 and Supplement 7S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Determinations shall be made of the need for supplier evaluation, source verification, supplier furnished documents, supplier nonconformance reporting, and receiving inspection. Appropriate provisions shall be included in procurement documents to meet the determined needs. Supplier evaluations, source verifications, and receiving inspections, when required, shall be performed by qualified personnel in accordance with approved procedures and instructions. Supplier documentation including Nonconformance Reports shall be reviewed and approved or accepted. Determinations shall be made of the acceptability for use of purchased items. Supplier performance shall be evaluated.

Responsibilities

Significant responsibilities include:

Requesting Organization

Ensuring that Inspection/Test Instructions are prepared and used when independent receiving inspection activities are performed.

Performing receiving inspection activities other than independent receiving inspection.

Contracts

Obtaining items and services from responsible suppliers.

Performing interface responsibilities between PNL and the supplier on deliverables, resolution of problems, and the scheduling of surveillances, audits, reviews, and inspections.

Quality Programs Staff

Performing preaward surveys, source verifications, and periodic audits of suppliers.

Reviewing supplier documents submitted in response to QA clauses.

Coordinating independent receiving inspection activities, and determining the acceptability of items for use.

Obtaining material overchecks on selected materials.

Selecting individuals for performance of inspection activities.

7.2 Control of Work Package Items and Services

Purpose

Controls are exercised over items and services obtained through Work Packages (including Work Orders) to ensure that the items and services conform with specified requirements.

Instructions, procedures, and drawings prepared by the performing organization (except for calibration procedures) are reviewed and approved by the requesting organization and Quality Programs to ensure the adequacy of their technical and quality assurance provisions. Reviews are made before new types of work are performed to verify the performing organization's readiness. Inspections, surveillances, and reviews, as appropriate, are made of the work performed to verify that it complies with requirements.

Section 4.2, "Work Package Control," describes the controls that are used to ensure that Work Package documents are complete and correct.

The degree of control exercised over work performed depends on its impact level and complexity.

Requirements

When fully applied, the methods included in the administrative procedures and referenced documents in the Policy and Procedure System meet the applicable requirements of DOE Order 5700.6C and Basic Requirement 7 and Supplement 7S-1 of NQA-1. Because Work Package items and services are obtained from other PNL organizations or from Hanford Contractors, some of the Criterion 7 requirements are not strictly applicable. These include:

- bid evaluation, since there are no bids

- receiving inspection, which is rarely performed -- Acceptance is usually based on hold point inspections during the performing organization's in-process or final inspection.

- the use of certificates of conformance

- the control of commercial grade items.

The significant requirements from the administrative procedures are summarized in the following paragraph.

The performing organization's procedures shall be reviewed and approved for their adequacy for meeting specified requirements. The performing organization's readiness to perform work to new procedures shall be evaluated before the start of work. Work shall be performed in accordance with all applicable requirements. Inspections, surveillances, and/or reviews of completed work shall be performed to verify its quality. Nonconformances in hardware or data shall be documented and resolved. Records of the achievement and verification of quality shall be provided. Records shall be kept of the quality history of the performing organizations.

Responsibilities

Significant responsibilities include:

Requesting Organization

With Quality Programs, reviewing and concurring in drawings and technical procedures prepared by the performing organization specifically for the work to be done, other than calibrations.

As necessary, releasing the performing organization to begin work after verifying its readiness to proceed.

Reviewing data furnished by the performing organization for reasonableness and for compliance with applicable requirements.

PNL Performing Organization

Providing the drawings and technical procedures required for the work.

Committing to applicable administrative procedures.

When specified, deferring the start of work until the readiness for performing such work has been reviewed.

Performing the work in accordance with all applicable and approved requirements and procedures.

Notifying Quality Programs of any hold points for inspection or surveillance, and observing these points.

Reporting and obtaining resolution of any nonconformances in data or hardware in accordance with Section 15.1, "Control of Nonconforming Items".

Attesting to the validity of reported data.

Quality Programs Staff

Participating in reviews of readiness for performing work.

Performing required inspections and surveillances, and accepting physical items furnished by the performing organization.

Maintaining and evaluating records of the performing organization's quality history.

8.1 Identification and Control of Items

Purpose

Items to be used in processes are identified and controlled to ensure that they are correct for their application, acceptable for use, and traceable to their origin. The validity and useability of data (or the assurance of end item quality) often depend on positive knowledge that effective identification and control of these items has been maintained throughout the R&D (or fabrication) process.

Requirements

When fully applied, the methods included in the administrative procedures for the identification and control of items and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 8 and Supplement 8S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Items that are available for use shall have Accept Tags attached or nearby. Items shall be identified and shall be traceable to their design or ordering documents. Incorrect or nonconforming items shall be controlled to prevent their inadvertent use. Limited life items shall be controlled to prevent use beyond their expiration dates. Materials used in fabrication shall be traceable to their origin. Materials used in testing shall be traceable both to their origin and to the tests in which they are used.

Responsibilities

Significant responsibilities include:

Line or Project Organization

Providing identification and traceability for items that they receive, hold, and transmit.

Using only items that are known to be acceptable.

Preventing the use of incorrect, nonconforming, or overage items.

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9.1 Control of Processes

Purpose

Processes are performed by trained and qualified personnel, using correct methods and materials, to ensure that the end results of the processes will be satisfactory (e.g., that resultant data will be valid). Instructions, procedures, and drawings are also used in process performance whenever there is a reasonable likelihood that without them the process will be accomplished incorrectly, with unacceptable or undesirable results. These documents are not usually used when simple processes such as weighing and reagent makeup are performed.

Special process controls are applied to processes whose end results cannot be fully inspected to provide assurance that the results are acceptable. Typical special processes include welding, nondestructive examination (for item acceptance purposes), heat treating, painting, coating, and bonding.

Section 5.1, "Instructions, Procedures, and Drawings," establishes the requirements for instructions, procedures, and drawings that may be used in processes or special processes. Section 11.1, "Test Control," describes the specific use of process control in testing.

Requirements

When fully applied, the methods included in the administrative procedures for the control of processes and special processes reference documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 9 and Supplement 9S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraphs.

Processes shall be controlled by ensuring that they are performed by trained and capable personnel, using correct materials and equipment. When required by Section 5.1, "Instructions, Procedures, and Drawings," process controls shall also include the use of instructions, procedures, and drawings which provide, as appropriate, for proper conditions, methods, sequences, verifications, and records.

Special processes shall be controlled through the use of qualified procedures, personnel, and equipment. The procedures shall be consistent with applicable codes and standards. Evidence shall be provided that special processes are performed using the qualified procedures, personnel, and equipment. The qualification and correct performance of special processes shall be verified.

Responsibilities

Significant responsibilities include:

Project or Line Organization

Ensuring that all processes satisfy the minimum requirements for process control.

Determining the need for instructions, procedures, and drawings in the control of processes, providing them, and ensuring their adequacy when required.

Providing qualified procedures, personnel, and equipment for the performance of special processes.

Adhering to applicable instructions, procedures, and drawings in the performance of processes and special processes.

Quality Programs Staff

Participating in the qualification of procedures, personnel, and equipment for special processes.

Providing surveillance of processes and special processes.

10.1 Inspection

Purpose

PNL inspections are performed and documented to verify that activities and items conform to specified requirements, inspection activities are planned, methods are specified, and acceptance criteria are provided.

Surveillances are conducted to verify that activities are performed correctly. Surveillances are planned to ensure thorough and periodic coverage.

Overall risk is a significant factor in determining the amount of surveillance a project or activity will receive. Overall risk is considered when planning for independent inspections; however, risk is not the sole determining factor.

Requirements

Methods included in the administrative procedures for inspection and surveillance and referenced documents in the Policy and Procedure System meet DOE Order 5700.6C and Basic Requirement 10 and Supplement 10S-1 of NQA-1 as interpreted for PNL activities. The significant requirements from administrative procedures are summarized in the following paragraphs.

Activities and items with associated documentation shall be inspected for conformance with applicable requirements. Inspection planning shall identify the characteristics to be inspected, the acceptance criteria, and the methods to be employed. Hold points for inspections shall be established, as necessary, and shall be honored. Inspections for acceptance shall be performed by qualified personnel who are independent of those who performed or supervised the work being inspected. Inspection results are documented to provide evidence of the item's acceptability. Records of inspection shall be maintained.

Process monitoring shall be used instead of, or with, inspection when direct inspection alone is insufficient.

Surveillances of activities shall be performed at periodic intervals or at important process steps. Surveillance planning shall identify the activities to be covered, acceptance criteria, when applicable, and when the surveillance is to occur. Responsible management shall be informed of surveillance results so appropriate actions can be taken.

Section 7.1, "Control of Purchased Items and Services," establishes the requirements for the use of inspection in the procurement process.

Responsibilities

Significant responsibilities include:

Project or Line Organizations

Performing or obtaining required inspections, as applicable.

Notifying Quality Programs of upcoming hold points for inspection or surveillance.

See also the responsibilities for Requesting Organization in Section 7.1, "Control of Purchased Items and Services".

Quality Programs Staff

Planning, performing, and documenting independent inspections.

Performing and documenting reviews of records that provide evidence of item acceptability.

Planning, performing, documenting, and reporting surveillances including determining Priority Planning Grid (PPG) values for conditions identified during internal surveillances and surveillances of Hanford Contractors.

11.1 Test Control

Purpose

Experimental testing is controlled to provide a high level of confidence in the validity and traceability of the resultant data. Testing to determine an item's acceptability also is controlled in order to ensure that the determinations are correct.

Test requirements are formalized to ensure that the tests will satisfy client needs. Test procedures and instructions are provided for the reasons given in Section 5.1, "Instructions, Procedures, and Drawings". Acceptance criteria are provided when testing is done for acceptance purposes, so that those performing the test will be able to determine objectively whether or not the item is acceptable. Testing is done by appropriately trained and qualified persons to ensure that the testing will be done correctly and that the results will be accepted as valid. Testing results are recorded so as to be traceable to the materials and equipment used, and to the specific test parameters. Results are evaluated to ensure that they indeed are valid and that they satisfy the test requirements.

The extent to which the requirements of this section are applied is a function of the impact level of the testing activity and of its complexity.

Requirements

When fully applied, the methods included in the administrative procedures for the control of testing and referenced documents in the Policy and Procedure System meet the requirements in DOE Order 5700.6C and Basic Requirement 11 and Supplement 11S-1 of NQA-1, except that requirements for acceptance criteria are applicable only when testing is being done to determine an item's acceptability. The requirements for Supplement 11S-2 of NQA-1 will be addressed in the next revision to the administrative Software Control Procedures. The significant requirements from the administrative procedures are summarized in the following paragraph.

Test objectives and requirements shall be documented and approved, and shall be consistent with client requirements. Test procedures and instructions shall be provided in accordance with Section 5.1, "Instructions, Procedures, and Drawings". Acceptance criteria shall be provided when testing is done to determine acceptability. Testing shall be performed by appropriately trained and qualified personnel. Test results shall be documented and shall be traceable to the materials, equipment, and test runs from which they were obtained. Test results shall be evaluated through independent technical reviews or peer reviews.

Responsibilities

Significant responsibilities include:

Project Organizations

Ensuring that test requirements are established, that they meet client requirements, and that they are maintained current.

Providing approved procedures and instructions, correct and traceable materials, proper test conditions, proper test equipment (including calibrated measuring and test equipment), and personnel training and qualification for the conduct of tests.

Conduct tests in accordance with all requirements.

Ensuring that supporting services to test activities, such as analytical work, satisfy their quality requirements.

Documenting test results so that they are traceable to the test conditions used and are retrievable.

Obtaining independent technical reviews or peer reviews of test procedures and test results.

Quality Programs Staff

Reviewing research project planning documents and technical procedures to verify that they include appropriate quality assurance requirements.

12.1 Control of Measuring and Test Equipment

Purpose

Controls are established for measuring and test equipment (M&TE) to ensure the integrity and validity of the data and to ensure that the M&TE are properly calibrated. Proper selection of M&TE is essential to meeting specified accuracy and precision requirements. M&TE require calibration at prescribed intervals to established standards to provide assurance that data or product integrity is maintained. Documented evaluation of the impact on data and products of out of tolerance M&TE is essential to ensure that previous measurements are acceptable. Calibration records are maintained to provide traceability to nationally recognized standards and objective evidence of control of the calibration process. M&TE require labels to identify the calibration status to the user.

Requirements

When fully applied, the methods included in the administrative procedures for the control and calibration of M&TE and referenced documents in the Policy and Procedure System meet the requirements of DOE Order 5700.6C and Basic Requirement 12 and Supplement 12S-1 of NQA-1. These methods do not apply to devices such as tape measures, burettes, pipettes, mercury thermometers, etc., if normal commercial practices are adequate for the application. The significant requirements from the administrative procedures are summarized in the following paragraph.

Selection and control of M&TE shall be performed by PNL staff. Controls shall include calibrating at prescribed intervals to established standards, documenting evaluation of impact on data/product when M&TE are found out-of-tolerance, maintaining records, and suitably marking M&TE to indicate calibration status. A measuring and test equipment control listing (including M&TE description, category, calibration interval, custodian, calibration agency, location, and control number) shall be used to assist in the control of M&TE.

Responsibilities

Significant responsibilities include:

Using Organization

Ensuring that M&TE are properly selected, identified, calibrated, and controlled.

Assigning responsibility for maintenance of M&TE records and M&TE control listings.

Ensuring that evaluation of discrepant M&TE is performed by cognizant personnel.

Quality Programs Staff

Verifying that documentation of discrepant M&TE is reviewed and an evaluation of impact on systems, product, or data is performed.

Compiling a history of discrepant M&TE and verifying that an evaluation is performed on M&TE consistently found out of calibration and that necessary corrective action is implemented.

Calibration Organization

Ensuring that calibration Category 1 M&TE are calibrated using standards with an established history of stability, known valid and documented relationships to nationally recognized standards, and accuracies that are at least four times better than those of the M&TE being calibrated unless limited by state of the art.

Performing calibration services for Category 1 M&TE to a formal statement of work.

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13.1 Handling, Storage, and Shipping

Purpose

Control of handling, storage, and shipping activities can reduce unnecessary damage, deterioration, or loss of equipment and materials. Controls ensure that items receive adequate protection against such conditions as temperature extremes, humidity, dust, shock, oxidation, bearing set, or shaft bowing.

Requirements

When fully applied, the methods included in the administrative procedures for handling, storage, and shipping of items and referenced documents in the Policies and Procedures System meet the requirements of DOE Order 5700.6C and Basic Requirement 13 and Supplement 13S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

PNL staff shall prepare written instructions for the handling, storage, and shipping of items where normal routine methods will not suffice. Special technical procedures shall be provided by PNL staff for the handling, storage, and shipping of critical, sensitive, perishable, or high-value items. Cognizant managers shall ensure that such written instructions or special procedures are implemented by personnel performing the work. The controls required by this section are primarily dependent on the impact level of the item and the potential for the item to be damaged if special controls are not used.

Responsibilities

Significant responsibilities include:

Cognizant Organization

Ensuring that necessary direction is determined and provided for the handling, storage, and shipment of items.

Providing and ensuring implementation of special technical procedures for critical, sensitive, perishable, or high-value items when normal, routine methods are insufficient.

Ensuring that operators of special handling tools and equipment are trained or experienced in the use of the equipment.

Ensuring that special handling tools and equipment have been maintained and have been tested and inspected within the specified time intervals.

Ensuring that items are marked and labelled as required by instructions or special procedures.

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14.1 Inspection, Test, and Operating Status

Purpose

The status of inspection, test, and operating conditions is identified to reduce the possibility of inadvertently using uninspected and untested items, or of operating controls and equipment when such operation may result in personnel injury, property damage, or loss of data.

Requirements

When fully applied, the methods included in the administrative procedures for identifying the inspection and test status of items and referenced documents in the Policies and Procedures System meet the requirements of DOE Order 5700.6C and Basic Requirement 14 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

PNL staff shall ensure that items are properly identified as to status. When appropriate, PNL staff shall use Accept, Hold, Reject, Conditionally Accepted, and Test In Process Tags.

Responsibilities

Significant responsibilities include:

Cognizant Organization

Attaching and removing status indicators as directed by procedure or other governing document to ensure required inspections and tests are performed and to ensure that items which have not passed the required inspections and tests are not inadvertently installed, used, or operated.

Using Nonconformance Reports, Inspection/Test Instructions, Deficiency Reports, calibration labels, and Calibration Discrepancy Tags as required by Sections 7.1, "Control of Purchased Items and Services", 12.1, "Control of Measuring and Test Equipment", and 15.1, "Control of Nonconforming Items".

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15.1 Control of Nonconforming Items

Purpose

Controls are established for the documentation, control, and disposition of nonconforming items to prevent their inadvertent use. Controls are also provided for the documentation of deviations from QA requirements and established procedures so that the deviations can be evaluated for impact on the integrity and validity of the work and corrective action taken to prevent future occurrences.

Requirements

When fully applied, the methods included in the administrative procedures for control of nonconforming items and deviations from QA requirements, established procedures, and referenced documents in the Policies and Procedures System meet the requirements of DOE Order 5700.6C and Basic Requirement 15 and Supplement 15S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraph.

Nonconforming items shall be identified, documented, controlled, evaluated, and dispositioned. Deficiencies shall be documented, evaluated, and resolved.

Responsibilities

Significant responsibilities include:

Initiating Organization

Identifying, segregating, or otherwise controlling and documenting nonconforming items.

Withholding nonconforming items from use until approval of the disposition has been obtained and any necessary repair or rework done.

Documenting deficiencies.

Verifying and documenting that the disposition has been performed as directed.

Using Organization

Determining the impact of a deficiency on research project results.

Implementing corrective actions to resolve the deficiency.

Identifying any project results affected by the deficiency and noting the location of corrected project results.

Approving the disposition of nonconforming items.

Contracts

Communicating deviation information to suppliers and obtaining dispositions.

Quality Programs Staff

Verifying that reviewers have signed and dated each Deficiency or Nonconformance Report and determining if additional reviews are required.

Transmitting a copy of such documentation to the organization responsible for performance of the disposition.

Verifying that disposition action has been taken, when appropriate.

Periodically analyzing Nonconformance Reports for quality trends.

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16.1 Corrective Action

Purpose

Conditions adverse to quality are reported and corrected. Significant conditions adverse to quality are reported, causes are determined, and corrective action is taken to minimize the likelihood or recurrence.

Requirements

When fully applied, the methods included in the administrative procedures for addressing conditions adverse to quality and significant conditions adverse to quality and referenced documents in the Policies and Procedures System meet the requirements of DOE Order 5700.6C and Basic Requirement 16 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraphs.

Nonconformances and deviations shall be documented and corrected, and trend analysis shall be performed to identify significant conditions adverse to quality. Significant conditions adverse to quality may also be found through various assessment activities. Such conditions shall be documented, causes determined, and corrective action taken to remove the causes.

Section 15.1, "Control of Nonconforming Items", includes requirements for the correction of nonconformances and deficiencies.

Section 10.1, "Inspection", and section 18.1, "Audits", include requirements for corrective action resulting from surveillances and audits. A graded approach for the correction and prevention of conditions identified during surveillances and audits is used. Priority Planning Grid values (PPG) are determined for each condition and corrective action requirements are based on the PPG value.

The determination of when a condition adverse to quality is significant is partly a function of the impact level of the items, including data, that the condition affects or could affect in the future if not corrected.

Responsibilities

Significant responsibilities include:

Cognizant Organization

Periodically evaluating documents received or initiated pertaining to nonconformances or deficiencies in their area of responsibility and reporting the results.

Determining, implementing, and completing the actions required in response to requests for corrective action.

Contracts

Processing Corrective Action Requests through suppliers.

Quality Programs Staff

Initiating a Corrective Action Request when there is a supplier-related significant condition adverse to quality.

Concurring with the planned actions in response to Corrective Action Requests.

Verifying satisfactory implementation of corrective actions before closing out a Corrective Action Request.

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17.1 Quality Assurance Records

Purpose

PNL maintains a records system to ensure availability of documented evidence of activities performed. This system provides for the protection against loss, damage, or deterioration of records. It also provides for the identification, storage, retrieval, and final disposition of these records.

Requirements

Methods included in the administrative procedures and referenced documents in the Policies and Procedures System meet the requirements of DOE Order 5700.6C and NQA-1 Basic Requirement 17 and Supplement 17S-1 quality assurance record requirements.

Detailed instructions for implementing the record system are in the administrative procedures. Included are in-process requirements for record generators and custodians to follow while maintaining the records in working files. Also, included are transfer and storage requirements once activities documented by the records are complete. The following activities/responsibilities are addressed by the requirements of the records system:

- records planning

- responsibilities of the records custodian

- identification and validation of the records

- record maintenance while in the possession of the record custodian

- record retention and maintenance

- record storage

- transfer and transmittal of completed records

- requests for stored records

- final records disposition.

Responsibilities

Significant responsibilities include:

Records Generating Organization

Identifying the appropriate schedule and retention period for records.

Preparing a Records Inventory and Disposition Schedule/File Index (RIDS).

Filing records and protecting them from damage or loss.

Disposing of records under the governing schedule.

Records Management and Document Control Manager

Administering the PNL records management program.

Approving Records Inventory and Disposition Schedule/File Index (RIDS) forms.

Approving project records management plans and procedures that contain special client records requirements.

Ensuring that records are dispositioned in accordance with requirements.

Coordinating turnover of records to the client, when required.

Arranging for retirement of records to an appropriate storage facility. (DOE Records Holding Area or PNWD Records Center.)

18.1 Audits

Purpose

Audits are performed to verify compliance and determine effectiveness of all aspects of the Quality Assurance Program and to determine where corrective action is needed. Timely corrective action is taken in order to correct the specific deficiencies identified and to prevent future occurrences of the same or similar deficiencies. Follow-up is performed to ensure that timely and effective corrective action is taken in response to identified deficiencies.

Requirements

When fully applied, the methods included in the administrative procedures for the audit function and referenced documents in the Policies and Procedures System meet the requirements of Basic Requirement 18 and Supplement 18S-1 of NQA-1. The significant requirements from the administrative procedures are summarized in the following paragraphs.

Audits shall be systematically scheduled, planned, performed, and reported. Written responses shall be provided to conditions identifying the cause and noting corrective action measures taken or to be taken to prevent recurrence. Corrective action commitments shall be implemented and tracked. Performance of audits on organizations external to PNL shall be coordinated through the cognizant management or contract representative.

Auditing is only one of the assessment activities required by DOE Order 5700.6C. The requirements included in the administrative procedures and in PNL-MA-531, *Quality Programs Instructions*, for auditing are consistent with the guidance included in DOE Order 5700.6C for assessments. Other types of assessment (e.g., reviews, inspections, surveillances) are addressed in other sections of this manual. PNL-MA-41, *PNL ES&H Self-Assessment Management Program*, describes the PNL Integrated Self-Assessment Program.

Responsibilities

Significant responsibilities include:

Audited Organization

Investigating deficiencies from audits and identifying the cause of the deficiencies.

Defining, scheduling, and implementing corrective actions for the cause and for the specific deficiency, including measures to prevent recurrence.

Quality Programs Staff

Scheduling and performing audits.

Determining Priority Planning Grid (PPG) values for conditions identified during internal audits and audits of Hanford Contractors.

Reporting audit results to affected organizations.

Reviewing audit responses for adequacy and reporting audit completion.

Performing follow-up, as necessary, to verify completion of corrective action.

Contracts

Arranging for the performance of audits of suppliers by PNL.

Transmitting and receiving audit correspondence between the supplier and PNL.

Obtaining corrective action from the supplier to audits.

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G-1 Acronyms

(Software terms marked with an *)

A-E	Architect Engineer
ARL*	Application Record Log
ASME	American Society of Mechanical Engineers
CAP-70-XXX	Contracts Administrative Procedures
CASE	Coordinating Agency for Supplier Evaluation
CDL	Controlled Document List
CDR	Conceptual Design Report
CDT	Calibration Discrepancy Tag
CDTR	Controlled Document Transmittal Record
CFR	Code of Federal Regulations
CNR	Contractor Nonconformance Request
D&DS	Design and Drafting Services
DCR	Document Change Request
DFC	Hanford Design/Field Change
DML*	Data Management Log
DOE	Department of Energy
DR	Deficiency Report
DRR	Document Review Record
DS	Documentation Systems Department
EDP	Engineering Design Plan
FDC	Functional Design Criteria
FIDR*	Final Internal Development Review
HEPA	High Efficiency Particulate Air
HFTF	Hanford Filter Test Facility
HIQS	Hanford Index of Qualified Suppliers
IC&E	Instrument Calibration and Evaluation
ICN	Interim Change Notice
IL	Impact Level
ILA	Interlaboratory Authorization
ITI	Inspection/Test Instructions
ITR	Independent Technical Review
KEH	Kaiser Engineers Hanford
LRB	Laboratory Record Book
MIC	Material Identification Card
M&TE	Measurement and Test Equipment
MP	Management Plan
MPO	Memorandum Purchase Order

NCR	Nonconformance Report
NDE	Nondestructive Examination
NQA-1	ASME NQA-1, Quality Assurance Program Requirements for Nuclear Facilities
OJT	On-the-Job Training
PAP-70-XXX	PNL Administrative Procedures
PM	Preventive Maintenance
PMP	Project Management Plan
PNL	Pacific Northwest Laboratory
PNWD	Pacific Northwest Division
PO	Purchase Order
PPD	Project Plan Document
PPG	Priority Planning Grid
PQ	Process Quality Department
PQE	Procurement Quality Engineer
PR	Purchase Requisition
PRCR	Peer Review Comments and Resolution
QA	Quality Assurance
QE	Quality Engineer
QIM	Quality Information Management Program
QP	Quality Programs Directorate
QP&A	Quality Planning and Assessment Department
RA&C	Regulatory Analysis and Compliance Program
RCC	Requisition Control Clerk
RFAS	Request for Analytical Services
RFP	Request for Proposal
RFT*	Request for Transfer
RFW	Request for Work
RIDS	Records Inventory and Disposition Schedule/File Index
RL	Richland Operations Office
SAE	Society of Automotive Engineers
SCP-70-XXX	Software Control Procedures
S/N	Serial Number
SOW	Statement of Work
SSCs	Systems, Structures, and Components
SSO	Source Selection Official
TI	Test Instruction
TPC	Technical Procedure Coordinator
TPP	Technical Program Plan
WBS	Work Breakdown Structure
WHC	Westinghouse Hanford Company
WO	Work Order

G-2 Glossary (Non-Software)

This glossary contains definitions of certain non-software
quality-related terms used in the administrative procedures.
[For definitions for the software control procedures (SCPs)
see G-3, Computer Software Glossary.]

Acceptance Criteria	Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.
Accuracy	The closeness of agreement between an observed or measured value and an accepted reference value. (Ref. Recommended practice, Medical Products And Pharmaceutical Industry Calibration Control Systems)
Activities Affecting Quality	Those activities that influence or affect the achievement or verification of quality objectives or requirements. These activities include, but are not limited to, the collection and analysis of data to be used by the client.
Administrative Procedures	For the PNL-MA-70 QA Program, the procedures that provide detailed requirements, methods, and responsibilities for Impact Level I and II and Safety Class items and activities. These procedures are contained in the Procedures for Quality Assurance Program (Part 3 of PNL-MA-70). The following types of procedures are included: PNL Administrative Procedure (PAP), Contracts Administrative Procedure (CAP), and Software Control Procedure (SCP).
Analytical Center	A PNL service group that provides analytical support to one or more projects. It may function either inside or outside the project organization.
Approval	An act of endorsing or adding positive authorization or both.
Approval Authority	The individual responsible for PNL approval for release (issue) of controlled documents and for establishment of the effective dates.
As-Built Data	Documented data that describes the conditions actually achieved in a material, component, part, system, or structure.
As-Built Drawings	Permanent drawings that depict the condition actually achieved in a material, component, part, or system after it is fabricated/constructed and accepted.
Calibration	Periodic and documented comparison to known standards to determine the accuracy of M&TE (to determine as-found condition and to adjust the equipment or to provide a calibration curve).
Category 1, 2, and 3	The three tiers used to classify M&TE. Category 1 M&TE is calibrated by a Process Quality Department evaluated metrology facility; Category 2 is calibrated by the using organization; and Category 3 does not require calibration.
Certificate of Conformance	A document signed by an authorized individual certifying the degree to which items or services meet specified requirements.
Certify	To determine, verify, and attest to, in writing, the qualifications of personnel, processes, procedures, data, items, or material, in accordance with specified requirements.
Characteristic	Any property or attribute of an item, process, or service that is distinct, describable, and measurable as to conforming or nonconforming with specified requirements.

Cognizant Manager	Includes managers of projects, functions, departments, and sections whose responsibilities are delineated in PNL-MA-70 or the administrative procedures.
Commercial Grade Items	Those products that are totally designed and available for commercial or industrial purchase. Items are usually described by the manufacturer with a unique catalog or model number or other means of specifically identifying the item. With the exception of manufacturer-provided and specifically defined product variations, options, and/or accessories, changes or modifications by the purchaser beyond that expressly provided or available from the manufacturer and not "off-the-shelf" or commercial grade.
Condition Adverse to Quality	An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one which, if uncorrected, could have a major adverse impact on the environment, health or safety, mission, cost, or reputation of PNL or the PNL client.
Conditional Accept	A disposition which accepts a nonconforming item for use, subject to specific restrictions.
Configuration	The functional, physical, and procedural characteristics of an item, experiment, or document.
Configuration Control	Knowing the present configuration and maintaining the knowledge by ensuring that changes are accomplished only in accordance with accepted change control methods.
Contract	A promise or set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty.
Contractor Nonconformance Request	A PNL document for use by a contractor to tender for acceptance nonconforming supplies or services at variance with the requirements of the contract.
Contract Specialist	An employee of Battelle-Northwest who issues RFPs and negotiates and executes contracts and agreements that are within the limits of a written delegation of authority from the Director, PNL. This definition includes PNL Buyers/Subcontract Specialists.
Corrective Action	Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.
Deficiency	Failure to develop, document, or implement effectively any applicable element of the QA Program or project activity established by mutual agreement with the client, or failure to follow established procedures.
Design	(1) Specifications, drawings, design criteria, and performance requirements. Includes designs at each stage of development (i.e., from conceptual to final design). (2) The act of conceiving, planning, and preparing specifications, drawings, and related documents.
Design Document	Written or pictorial information (e.g., drawings and specifications) which establish design, performance, environment, fabrication, installation, operation, or other requirements for the design fabrication or construction of an item, system, or structure.
Design Information and Design Activities	Data collection and analysis activities that are used in supporting design development and verification. Includes general plans and detailed procedures for data collection and analyses and related information such as test results and analysis. Data analysis includes the initial step of data reduction as well as broad-level systems analyses (such as performance assessments) which integrate many other data and analyses of individual parameters.

Design Input	Those criteria, parameters, bases, or other design requirements upon which detailed final design is based.
Design Output	Documents, such as drawings, specifications, and other documents defining technical requirements of structures, systems, and components.
Deviation	A planned or unplanned departure form specified requirements. A deviation may be a characteristic outside of specifications or failure to follow accepted, documented procedures. Frequently, planned deviations are permitted when written authorization (e.g., an interim change request notice)is obtained for the planned departure from the specified requirements. Unplanned deviations are handled as deficiencies and nonconformances.
Document	Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered to be a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record as defined in this manual.
Document Control	(1) The system used to control the issuance and disposition of documents (including changes) which provides for review for adequacy, approval for release by authorized personnel, and distribution to and use in the location where the prescribed activity is performed. (2) The PNL Publication Services and Records Management Department function responsible for reproduction and distribution of changes, the preparation and updating of lists of current documents or control registers (including changes), and other assigned functions of document control.
Engineering Design Plan	A form used within PNL for defining and documenting the requirements for design activities for which PNL will be responsible.
External Audit	An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.
Facility	A structure (e.g., a building) or portion thereof that is operated by PNL, including all attached systems (e.g., fire protection, HVAC, electrical, lighting, high pressure gasses/fluid, fluid transfer) whether or not wholly contained within the structure.
Hanford Contractors	The contractors to the Department of Energy for the operation of the DOE facilities at Richland, Washington. As used in the administrative procedures, excludes Battelle Memorial institute that operates the Pacific Northwest Laboratory (PNL) for DOE.
Hold Point	A point indicated in appropriate work documents beyond which work shall not proceed without the specific consent of the designated representative. Consent to waive specified hold points shall be recorded prior to continuation of work beyond the designated hold point.
Impact Level	One of three designations (Impact Levels 1, II, and III) assigned based on the consequence of a potential error or failure and used to assist in the selection of appropriate QA requirements.
Independent Technical Review	A documented critical review by qualified personnel to provide assurance that a document is correct and satisfactory. The review shall be performed by any competent individual(s) other than those who originated the document but who may be in the same organization. The review may be performed by the originator's manager provided the manager is qualified to perform a credible, objective appraisal and is the only individual in the organization competent to perform the review.

Indoctrination and Training	Includes all of the actions necessary (e.g., classroom sessions, on-the-job training, required reading assignments) to ensure that personnel assigned to manage or perform activities affecting quality are familiar with and understand the purpose, scope, and implementation of the QA Program manuals, procedures, administrative controls, and interfaces applicable to their work assignments.
Inspection/Test Instructions	Specific written instructions for performing inspection or testing that are prepared, reviewed, and approved using the instructions in Exhibit 1 of PAP-70-702, Preparation and Use of Inspection/Test Instructions, as a guideline.
Interim Change Notice	A form used for the purpose of making a correction or simple modification to a procedure or instruction that provides for identifying, describing in writing, approving, and issuing the change within a short period of time.
Interlaboratory Authorization	A agreement for the acquisition of materials or services from other Battelle components. (ILAs are not contracts.)
Internal Audit	An audit of those portions of an organization's quality assurance program retained under the organization's direct control and within its organizational structure.
Item	An all inclusive term used in place of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, sample (including field specimens such as mud, core, and water), geologic environment, prototypic hardware, magnetic media, computer printouts, computer software in any form, data, and documents.
Laboratory Record Book	A hardbound, uniquely identified, paginated book used to document research activities (see PNL-MA-68, *Records Management and Document Control*).
Line Manager	The appropriate manager within the administrative organization who has responsibility for the activity. Because different Department Managers within PNL have organized their departments and delegated their responsibilities in different ways, "Line Manager" may mean different levels in different departments. When used in the phrase, "...'s Line Manager," it means the administrative manager to whom the named person reports.
Measuring and Test Equipment (M&TE)	Devises or systems used to calibrate, measure, gauge, test, inspect, or control in order to acquire research, development, test, or operational data or to determine compliance with design specifications or other technical requirements. M&TE includes installed process measuring or monitoring gauges and instrumentation used for non-data purposes.
M&TE Custodian	Person assigned by research project management to be responsible for control of M&TE.
Memorandum Purchase Order	An agreement for the delivery of material and/or the performance of services by a DOE integrated cost-reimbursement contractor not located at the Hanford site. (MPOs are not contracts.)
Nonconformance	A deficiency in characteristic, documentation, or procedure which renders the quality of an item unacceptable or indeterminate. Examples of nonconformances include physical defects, test failures, incorrect or inadequate documentation of data, or deviation from prescribed processing, inspection, or test procedures.
Nonconformance Report (NCR)	Form used to document, control, and disposition material or items found to be nonconforming.

Non-Safety Class   See Safety Class.

Objective Evidence   Any documented statement or fact, other information, record or data, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified (e.g., record of site characteristics based on documented surveys, measurements, or tests).

Peer Review   A documented, fully traceable, review performed by qualified personnel who are independent of the original work performed or to be performed but have the technical expertise to perform the work (i.e., peers). Peer reviews are in-depth, critical reviews and evaluations of project documents, material, or data that require interpretation or judgement to verify or validate results or conclusions; or when the conclusions, material, or data contained in the report go beyond the existing state-of-the-art.

Permanent Engineering Drawing   Engineering drawings of facilities and equipment of a permanent nature which could be required to be reproduced after the initial construction, fabrication, or release for general use. Permanent engineering drawings for DOE facilities or 1830 and 1830-related services clients have numbers prefixed by H-. Drawings for Battelle facilities or non-1830 R&D clients have numbers prefixed by R- or have a client-furnished numbering system.

Preaward Survey   An evaluation made prior to contract award, or as a condition of award, to assess an organization's technical, quality assurance, production, or financial capability, including its quality program/system, to meet the requirements specified in a request for proposal or a contract.

PQD-Evaluated Supplier   A supplier who has been evaluated by the Process Quality Department and determined capable to provide certain defined items or services (e.g., special processes, calibration, and material control) and to implement specified quality assurance measures.

Priority Planning Grid Value   A number that is assigned to a condition identified during certain assessment activities and used to assist in determining the corrective action requirements (see PNL-MA-41, *PNL ES&H Self-Assessment Management Program*).

Procurement   The obtaining of specified items or services from a supplier.

Procurement Document   Purchase requisitions, purchase orders, memorandum purchase orders, store orders, work orders, interlaboratory authorizations, drawings, contracts, specifications, or instructions used to define requirements for purchase.

Project   A specific assignment of work and resources [typically described by Work Package Agreements (WPAs), Field Task Proposal/Agreements, Form 189A, or contracts.]

Project Contributors   PNL research staff as well as PNL support groups.

Project Files   The working area file cabinets and drawers containing project records in various states of completion.

Purchaser   The organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.

QA Plan	A document that identifies the requirements from PNL-MA-70 and the administrative procedures that are expected to apply to the work covered by the QA Plan. QA Plans also identify any additional QA requirements from the client, the responsible individuals and organizations, any exceptions, and any special factors that need to be considered.
QP Representative	A nonsecretarial/nonclerical Quality Programs staff member authorized to represent the QP Directorate.
Qualification (Personnel)	The characteristics or abilities gained through education, training, or experience as measured against established requirements, such as standards or tests that qualify an individual to perform a required function.
Qualified Procedure	An approved procedure that has been demonstrated to meet the specified requirements for its intended purpose.
Quality	The degree to which an item or process meets or exceeds the user's requirements and expectations.
Quality Assurance	Actions that provide confidence that quality is achieved.
Quality Assurance Records	Completed documents that furnish evidence of the quality of items and/or activities affecting quality. When a project, task, deliverable, or activity is complete, the entire records package becomes a quality assurance record. Within the Standard Filing System, the file classification titled "Quality Assurance" is for filing documents that are generated due to the PNL Quality Program requirements (i.e., QA Plans, QA Audit Reports, Nonconformance Reports, Deficiency Reports). Other quality assurance records are filed according to the appropriate file classification (i.e., Administration, Personnel, Technical, etc.).
Quality Control	Those quality assurance actions which provide a means to control and measure the characteristics of an item, process, or facility to established requirements.
Quality-Related	Activities which are important to public health and safety, environmental protection, equipment performance and reliability, and in general, those which affect the achievement of project quality objectives.
Receiving	Taking delivery of an item at a designated location.
Receiving Inspection	An inspection performed in accordance with established procedures and inspection instructions, to verify by objective evidence such features as proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanness.
Receiving Inspection Organization	The organization designated to perform receiving inspection. Typical organizations include the requestor's organization, Process Quality Department, Craft Services, and the WHC Standards Lab.
Reject	A decision that a nonconforming item cannot be used as is, reworked, or repaired. Rejected items are either scrapped or returned to the source.
Repair	The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement. Any restoration in which a work process is used other than those used in the original manufacture shall be considered a repair.

Request for Work	A document that authorizes a specific unit of work to be performed in accordance with an approved Work Order/Statement of Work (Exhibit 4 of PAP-70-404, Obtaining Services).
Research Project	See "Project": The adjective "research" is sometimes added to clearly differentiate between a "construction project" as defined by the DOE and a "project" as defined by PNL.
Research Project Records Custodian	A person assigned by the Project Manager to review and control records generated by a research project.
Rework	The process by which a nonconformance is made to conform to specified design requirements within the processing requirements of the original work documents.
Right of Access	The right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.
Safety Class	One of two safety classifications assigned to systems, structures, and components (SSCs) in accordance with guidance in Section 7.0 of PNL-MA-44, *Safety Analysis*. The other classification is Non-Safety Class.
Services	The performance of activities supporting research projects, such as chemical and physical analyses, independent design calculations, calibration of M&TE, test equipment fabrication, or inspection services.
Service Group	A PNL section, subsection, or individual, or an organizational component within another Hanford Contractor that provides a service to a research project.
Service Manager	The manager or individual responsible for the service group's activity.
Shall, Should, May	"Shall" denotes a requirement that must be met, "should" denotes a recommendation or guideline, and "may" denotes permission but not a requirement. When a section or paragraph of this manual is selected in a QA Plan, "shall" is implied unless "should" or "may" is used in the applicable text.
Special Post-Receiving Inspection	May be comprised of either special testing (e.g., analysis) or special inspections, or both. The SPRI may act as: 1) the acceptance test of a purchased item having definitive specifications for operation or service, or 2) the demonstration of a process or a characteristic which satisfies a distinct empirical need and for which there are no specific pass/fail parameters or requirements.
Special Process	A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.
Standard Operating Procedure	Procedures that are routine in nature, and that are not normally limited to a specific series of experiments/tests. Examples include: operation of analytical equipment (e.g., pH meter) and routine chemical analysis.
Standard Quality Assurance Clauses	The contract clauses, Request for Proposal provisions, and notes contained in Exhibit 1 of PAP-70-401, Purchase Requisitions.
Statement of Work (SOW)	(1) A document that provides the technical and QA requirements applicable to a specific work order. (2) The section by that title in the 189 document or its equivalent.

Stop Work Request
A management tool to request stoppage of any activity that is not in substantial compliance with QA requirements or procedures, or of any activity for which corrective action is not implemented in a timely manner.

Supplemental Work Order
A document that authorizes a change to an existing Work Order (DOE Form No. 54-3000-244).

Supplier
Any individual or organization who furnishes items or services in accordance with a procurement document. An all inclusive term used in place of any of the following: vendor, seller, contractor, subcontractor, fabricator, consultant, and their subtier levels.

Surveillance
The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

Technical Document
A document of technical rather than financial, administrative, management, or contractual subject matter. Technical documents may include (but are not limited to) the following:

- technical reports such as topical reports, final reports, letter reports, or technical memoranda

- technical data used as the basis for programmatic decisions

- computer software and its documentation

- technical procedures

- nonadministrative documents that support project objectives, such as environmental impact statements or socioeconomic studies

- project experimental/test plans (or equivalent)

- field sampling plans.

Technical Procedure
A term used to describe procedures that are primarily technical in content including Test Procedures, Research Project Technical Procedures, Service Group Technical Procedures, and Standard Operating Procedures.

Technical Representative
An individual technically knowledgeable in the requirements for the items or services requested.

Technical Review
A documented evaluation of technical documents, material, or data that assesses the technical applicability, correctness, adequacy, and completeness of the reviewed documents. Technical reviews may be performed by an individual involved in the work performed but may not be the originator of the document being reviewed.

Temporary Engineering Drawings
Design drawings of facilities or equipment of a temporary nature where long-term storage of original tracings is not needed, such as conceptual layouts, prototype equipment, or where the information contained will be transferred to permanent drawings for record. These drawings have numbers prefixed SK- for DOE facilities, 1830 and 1830-related services R&D clients; drawings for Battelle facilities and non-1830 R&D clients are prefixed by an RSK- or a client-furnished numbering system.

Test Instruction (TI) An instruction document (or run plan) traceable to an approved Test Procedure that establishes the specific operating parameters and sample size and/or composition for a specific experiment/test run. The TI contains sufficient information to provide the basis for data traceability for each individual experiment/test run.

Test Procedure (TP) Procedures that are specific to a particular series of experiments/tests in which the steps of performance are fixed, but multiple runs are expected for variation of the operating parameters and sample size and/or composition.

Testing An element of verification for acquisition of data or for the determination of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental, or operating conditions.

Traceability The ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Use-As-Is A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verify To review, inspect, test, check, compare, audit, or otherwise determine, confirm, substantiate, or ensure that items, activities (including field and laboratory), data, data analysis and interpretation, processes, services, and documents conform to, or have been implemented in accordance with, specified requirements, procedures, plans, etc.

Waiver A documented authorization to temporarily depart from specified requirements.

Witness Point A point indicated in appropriate work documents beyond which work shall not proceed without the required notification of the designated representative. Notification shall be documented. Witnessing at the point is at the option of the representative.

Work Order A document that authorizes funding for a discrete activity or service (DOE Form No. 54-3000-338).

Work Package The lowest level of work authorization for work to be done within PNL. As used in the administrative procedures, includes Work Orders when work is obtained form Hanford Contractors.

Worksheets Sketches, diagrams, and other delineations that constitute background or supplemental data that do not require formal checking, record copies, or other acquisition requirements. These worksheets have unique numbers designated by the person responsible for the work.

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G-3 Computer Software Glossary

Acquired Software Design Documentation	Software and/or design documentation obtained by procurement or transfer from outside the research project.
Application	See application run.
Application Run	Use of software to perform calculations or to manipulate data. Same as application.
Backup Copy	A copy of a data file, software, etc., on magnetic media or as a computer listing that is retained in the event that the original copy is destroyed or lost.
Benchmarking	A type of verification in which a test problem (including input and output results) is used to ensure correct model operation or to compare software.
Class Determination	Designation of software into a category. The selection of a category in turn determines other requirements.
Code	See software.
Code Custodian	A person designated to be responsible for accomplishing the actions required for configuration management; this individual is generally the main point of contact and authority for a given computer code.
Computer Model	Engineering/scientific software and data.
Configuration Management	1. A system for orderly control of software, including methods used for labeling, changing, and storing software and its associated documentation. 2. The systematic evaluation, coordination, approval or disapproval, and implementation of all approved changes in an item of software after establishment of its configuration management (taken from DOD-STD-480A).
Conversion Testing	Testing performed to ensure that calculated results obtained with software installed on a specific computer are consistent with results obtained on the computer on which the software was originally developed and tested.
Data	1. Representation of facts/concepts in a formalized manner suitable for communication, interpretation, or processing by human or automatic means. 2. Any representation such as characters or analog quantities to which meaning is or might be reassigned. 3. Same as input data, numeric data, output data.
Database	A logically unified collection of information stored on magnetic media and maintained by a research project. Within the SCP series, a flat (sequential) file or a binary worksheet (e.g., from SAS or MINITAB) containing a collection of information in a fixed configuration is considered a database when it is used as the information base for a research project.
Database Software	Software that handles storage and retrieval of information in a database. This software is often known as a database management system (DBMS). Analytical software (e.g., SAS or MINITAB) is regarded as database software when it is used to manage a database.
Database Steward	A person designated to be responsible for accomplishing the actions required for configuration management of a database.

Deficiency	Failure to develop, document, or implement effectively any applicable element of the QA Program or project activity established by mutual agreement with the client, or failure to follow established procedures.
Design Documentation	1. For engineering/scientific software, documentation of software design that includes a description of mathematical models and numerical methods, and a user's manual. 2. For support software documentation of software that includes at a minimum a user's manual.
Design Input	1. Input to the software development process, including bases for software design, performance requirements, regulatory requirements, and codes and standards (taken from ASME NQA-1-1989, Supplement 3S-1). 2. Also termed "software requirements specifications:" functions, performances, design constraints, and attributes of software and external interfaces (taken from IEEE std 730-1984).
Documentation	Design documentation and exhibits, memos, and/or other information used to ensure traceability and reproducibility of software development, review, control, testing, and use.
Engineering/ Scientific Software	Software that reads input data, computes results, and provides output calculations for use in performing an analysis or making an inference. Engineering/scientific software may be transferred from outside PNL or outside the research project, or it may be developed at PNL. Transferred software may be used as acquired, or it may be modified at PNL. (NOTE. Does not include system maintained software, such as LOTUS 1-2-3, RS/1, SAS, or DISSPLA, or command files written to utilize such software.)
Final Internal Development Review (FIDR)	A formal review process that compares modified or developed engineering/scientific software and its review documentation to its design input and design documentation requirements, evaluates the technical validity of the software, and approves software for configuration control and verification and/or validation.
Hard Copy	A computer-produced copy of information in human-readable form on paper or microfiche (as opposed to a copy on magnetic media in computer-readable form).
Incident	Any deviation from the planned or expected behavior of an activity or operation; or a course of events which has or may have a significant programmatic, safety, health, or environmental impact. Significant programmatic impacts include those associated with reliability, cost, schedule, data loss, or questions of data validity or analysis.
Independent Technical Review (ITR)	A documented critical review by qualified independent personnel to provide assurance that information is correct and satisfactory.
Internal Testing	Informal testing of software that is performed during the development process. Internal testing does not replace verification but may be used to support the verification process.
Magnetic Media	Tapes, disks, or diskettes used to record and store information in computer-readable form.
Operating System Software	A collection of software remaining permanently on a computer to provide overall coordination and control of the operation of the hardware. This collection includes compilers, link editors and similar software.
Project Manager	A person designated as the manager of a research project. The term project manager also refers to those persons designated by the project manager to act on his/her behalf for specific activities.

Production Software	Software for which the detailed design can be prespecified to a level of detail acceptable for development (as opposed to research software).
Program	See software.
Research Project Planning Documents	Documents that specify agreements between PNL and a client regarding the nature of work to be performed in a research project. Examples of these documents are the Project Management Plan (PMP), the Technical Program Plan (TPP), the Quality Assurance Plan (QA Plan), the Statement of Work (SOW), and the Field Task Proposal/Agreement (FTP/A).
Research Software	Software for which the detailed design is being researched in the software development process, and for which comprehensive, accurate prespecification of design detail usually is not possible (as opposed to production software).
Secure Storage	Controlled access, limited to individuals that are authorized for specific purposes.
Software	A sequence of instructions suitable for processing by a computer. Same as program, code.
Software Development	The process by which new software (or a software segment) is created, including modification of the logic of existing software.
Stream of Commands	A sequence of instructions executing system maintained software that is supplied by the user for an application run.
System Maintained Software	Software that is installed and maintained at the computer system level rather than at the user level, but that is peripheral to the operation of the hardware (e.g., commercial software such as LOTUS 1-2-3, RS/1, SAS, OR DISSPLA).
Support Software	1. Software that may be easily and exactly verified, and that performs a simple function such as conversion of units, change in data format or plotting of data in support of engineering/scientific or system maintained software. 2. A stream of commands or sequence of streams of commands executed to utilize system maintained software, in which the system maintained software generates reportable results.
User's Manual	Documentation of software that supplies information to the user to allow preparation of input and understanding of format and/or content or output.
Validation	1. A demonstration that a computer model (data and software) adequately describes physical reality over the range of variables of interest. 2. Assurance that a model as embodied in a computer code is a correct representation of the process or system for which it is intended (taken from NUREG-0856).
Verification	1. A demonstration that software correctly solves mathematical equations and performs the data processing it was designed to perform. 2. Assurance that a computer code correctly performs operations specified in a numerical model (taken from NUREG-0856).
Version	An item of software or documentation that is identifiably different from the original item.

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